DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 6, 2015

Heany Industries, Inc.
c/o Carrie Hetrick, DDS
Emergo Group
816 Congress Avenue, Suite 1400
Austin, TX 78701

Re: K150056
Trade/Device Name: Luxisse +
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Codes: EIH
Dated: February 6, 2015
Received: February 9, 2015

Dear Dr. Hetrick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
"Luxisse +"

Indications for Use *(Describe)*
Heany Industries, Inc. "Luxisse +" is non-implantable, machinable Zirconia material intended for CAD/CAM fabrication of all ceramic dental restorations. The material is used for the manufacturing of inlays, onlays, veneers, single unit anterior and posterior crowns, and three unit anterior bridges.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

for

"Luxisse +"

1. Submission Sponsor

Heany Industries, Inc.
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Scottsville, NY 14546
United States of America
Phone: (585) 889-2700
Fax: (585) 889-2708
Contact: Cliff Rabidoux, Senior VP

2. Submission Correspondent

Emergo Group
816 Congress Avenue, Suite 1400
Austin, TX 78701
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Office Phone: (512) 327.9997
Fax: (512) 327.9998
Contact: Carrie Hetrick, Senior Consultant, RA
Email: project.management@emergogroup.com

3. Date Prepared

5/4/2015

4. Device Identification

Trade/Proprietary Name:	"Luxisse +"
Common/Usual Name:	Porcelain powder for clinical use
Classification Name:	Powder, Porcelain
Classification Regulation:	21 CFR § 872.6660
Product Code:	EIH
Device Class:	Class II
Classification Panel:	Dental

5. Legally Marketed Predicate Device(s)

Heany Industries, Inc. Dental Zirconia 510(k) Number K073314 (Predicate)
VITA Zahnfabrik H. Rauter GmbH & Co. Vita Suprinity 510(k) Number K132070 (Reference)

6. Device Description

Heany Industries Inc. "Luxisse +" is an all ceramic core dental material made of Yttria-Stabilized Zirconium Oxide (zirconia, YSZ). It is provided as a block or disk shape. CAD/CAM

fabrication of core material can then be used to produce copings and substrates for fixed all ceramic dental restorations above the gum line. The material is used for the manufacturing of inlays, onlays, veneers, single unit posterior and anterior crowns, and three unit anterior bridges. The material is then fired in an oven to harden the ZrO_2. The milling and final oven hardening is completed by the customer.

7. Indication for Use Statement

Heany Industries, Inc. "Luxisse +" is non-implantable, machinable Zirconia material intended for CAD/CAM fabrication of all ceramic dental restorations. The material is used for the manufacturing of inlays, onlays, veneers, single unit anterior and posterior crowns, and three unit anterior bridges.

8. Substantial Equivalence Discussion

The following table compares the "Luxisse +" to the predicate device with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 1: Device Comparison Chart

Manufacturer	**Heany Industries, Inc.**	**Heany Industries, Inc (Predicate)**
Trade Name	**"Luxisse +"**	**Dental Zirconia**
510(k) Number	K150056	K073314
Product Code	EIH	EIH
Regulation Number	21 CFR § 872.6660	21 CFR § 872.6660
Regulation Name	Porcelain Powder for Clinical Use	Porcelain Powder for Clinical Use
Indications for Use	Heany Industries, Inc. "Luxisse +" is non-implantable, machinable Zirconia material intended for CAD/CAM fabrication of all ceramic dental restorations. The material is used for the manufacturing of inlays, onlays, veneers, single unit anterior and posterior crowns, and 3 unit anterior bridges.	Heany Industries Inc. Dental Zirconia is non-implantable material intended for CAD/CAM fabrication of core material used in all-ceramic dental restorations. The material is used for the manufacturing of inlays, onlays, veneers, crowns and bridges
Material (wt%)	Zirconia 99.8 wt% [$ZrO_2 + Y_2O_3 + HfO_2 + Al_2O_3$]	Zirconia 99.55-99.7 wt% [$ZrO_2 + Y_2O_3 + HfO_2 + Al_2O_3$]
Shapes	Blocks, disks	Blocks, disks
Dimensions	Various	Various
Supplied Sterile	No	No
Single Use	Yes	Yes
Bulk density, g/cm^3 (sintered)	6.05 g/cm^3	6.05 g/cm^3
Porosity	< 0.5 %	< 0.5 %
Flexural Strength, MPa (sintered)	546 MPa	1200 MPa ± 150 MPa
Fracture Toughness	5.83 MPam$^{0.5}$	8 MPam$^{0.5}$

Manufacturer	Heany Industries, Inc.	Heany Industries, Inc (Predicate)
Trade Name	**"Luxisse +"**	**Dental Zirconia**
Thermal Expansion:	10 x 10^{-6}/K	10 x 10^{-6}/K
Thermal Conductivity:	2.5 W/mK	2.5 W/mK
Chemical Solubility in Water:	< 10 µg/cm^2	-14 µg/cm^2
Sintering Temperature (°C)	1450 °C	1450 °C
Translucency	41% Transmittance	49% Transmittance

The "Luxisse +" device shares the same or similar indications for use, device operation, overall technical and functional capabilities, and therefore is substantially equivalent to the predicate device. All of the components have been used in legally marketed devices. The formulations have not been changed in ways that may adversely impact device performance.

9. Non-Clinical Performance Data

Non-clinical testing was performed in order to validate the design against the Company's specified design requirements for physical and chemical properties, as well as flexural strength, and to assure conformance with the consensus design standard ISO 6872:2008. "Luxisse +" is classified as Type II Class 1a and b, 2a, and 4b esthetic dental ceramic.

The disks and blocks can be fabricated into various prosthetic dental devices and the zirconia powder conforms to ISO 6872:2008, *Dentistry – Ceramic Materials* and BS EN 1641:2004, *Dentistry, Medical Devices for Dentistry, Materials*. The table below summarizes the results.

Table 2: Testing performed for the "Luxisse +" 510(k) Submission

Test	Conclusion
Radioactivity Concentration	The results meeting the predefined criteria as specified in ISO 6872: 2008 (E) supports a finding of substantial equivalence
Flexural Strength	The results met the requirements as specified in ISO 6872: 2008(E). Weibull statistics were used to better describe the distribution of strength. Ceramic materials exhibit unusually wide scatter in measured strength values due to a distribution of strength limiting defects. High variation in strengths cannot be accounted for solely by experimental error.
Uniformity	The results meeting the predefined criteria as specified in ISO 6872: 2008 (E) supports a finding of substantial equivalence.
Coefficient of thermal expansion (CTE)	The CTE results meeting the predefined criteria as specified in ISO 6872: 2008 (E) supports a finding of substantial equivalence.
Fracture Toughness (KIC)	The results meeting the predefined criteria as specified in ISO 6872: 2008 (E) supports a finding of substantial equivalence.
Chemical Solubility	The results meeting the predefined criteria as specified in ISO 6872: 2008 (E) supports a finding of substantial equivalence.

The “Luxisse +” meets all the requirements for overall design and biocompatibility, and performance testing confirms that the output meets the design inputs and specifications. The “Luxisse +” passed all testing stated above as shown by the acceptable results obtained.

The “Luxisse +” complies with the applicable voluntary standards for performance. The device passed all the testing in accordance with national and international standards.

10. Clinical Performance Data

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years and there are no adverse reactions. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device.

The “Luxisse +” has the same or similar intended use, indications, principles of operation, and technological characteristics as the predicate devices. “Luxisse +”, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate devices in terms of intended use, design, materials, and function.